PATENT COOPERATION TREATY

PCT

REC'D 10 MAY 2005

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| | icant's or agent's file reference | FOR FURTHER AC | CTION | See Form PCT/IPEA/416 | | |
|--|---|---------------------------------------|----------------------------------|--|--|--|
| REC | G/G20711WO | | | See Form FCT//FEAA-16 | | |
| | national application No. I/GB2004/001551 | International filing date (08.04.2004 | day/month/year) | Priority date (day/month/year) 10.04.2003 | | |
| | national Patent Classification (IPC) o | r national classification and IF | PC | | | |
| 1 | icant ZOPTIC LIMITED et al. | | | | | |
| 1. | This report is the international Authority under Article 35 and | | | nis International Preliminary Examining 36. | | |
| 2. | This REPORT consists of a tot | al of 9 sheets, including th | ils cover sheet. | | | |
| 3. | · · · · · · · · · · · · · · · · · · · | | | | | |
| İ | a. 🛛 sent to the applicant an | d to the International Bure | au) a total of 4 sheet | s, as follows: | | |
| | sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). | | | | | |
| sheets which supersede earlier sheets, but which this Authority considers contain an amendment that g beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. | | | | | | |
| | b. (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)), containing sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions). | | | | | |
| 4. | This report contains indications | s relating to the following it | ems: | | | |
| | ☑ Box No. I Basis of the | opinion | | | | |
| | ☐ Box No. II Priority | | | | | |
| | Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | | |
| ☐ Box No. IV Lack of unity of invention | | | | | | |
| | Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | | | | |
| ŀ | Box No. VI Certain docu | ments cited | • | | | |
| | | cts in the international app | | | | |
| | Box No. VIII Certain obse | rvations on the internation | al application | | | |
| Date | of submission of the demand | | Date of completion of | this report | | |
| 02. | 02.11.2004 | | 09.05.2005 | | | |
| Nam | ne and mailing address of the internal minary examining authority: | tional | Authorized Officer | chas Palanta | | |
| | Europea Munich Tel. +49 89 2399 - 0 Tx: 5 Fax: +49 89 2399 - 4465 | 23656 epmu d | Duijs, E Telephone No. +49 89 | 9 2399-7945 | | |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/GB2004/001551

| | Box | x No. I Basis of th | report | |
|----|---------------|---|---|--------------|
| 1. | Witl filed | th regard to the lang d, unless otherwise i | ge, this report is based on the international application in the language in which it icated under this item. | was |
| | | which is the languation international sea | on translations from the original language into the following language, e of a translation furnished for the purposes of: ch (under Rules 12.3 and 23.1(b)) international application (under Rule 12.4) ninary examination (under Rules 55.2 and/or 55.3) | |
| 2. | hav | ve been furnished to | nts* of the international application, this report is based on (replacement sheets we receiving Office in response to an invitation under Article 14 are referred to in the and are not annexed to this report): | /hich iis |
| | Des | scription, Pages | | |
| | 1-17 | 7 | as originally filed | |
| | Cla | ims, Numbers | | |
| | 1-2 | 25 | received on 02.11.2004 with letter of 29.10.2004 | |
| | Dra | awings, Sheets | | |
| | 1/7- | -7/7 | as originally filed | |
| | | a sequence listing | nd/or any related table(s) - see Supplemental Box Relating to Sequence Listing | |
| 3. | | ☐ the description,☐ the claims, Nos☐ the drawings, s☐ the sequence li | eets/figs | |
| 4. | had Su | d not been made, singlemental Box (Ru the description the claims, Nos the drawings, s the sequence li | ages eets/figs | low the |
| | * | If item 4 appl | es, some or all of these sheets may be marked "superseded." | |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/GB2004/001551

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

Claims

6,7,14,15,17-25

No:

1-5,8-13,16

Inventive step (IS)

Yes: Claims

No: Claims

1-25

Industrial applicability (IA)

Yes: Claims

1-25

No: Claims

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1. Reference is made to the following documents:
 - D1: WRIGHT J D ET AL: 'Development of a piezo-optical chemical monitoring system' SENSORS AND ACTUATORS B, ELSEVIER SEQUOIA S.A., LAUSANNE, CH, vol. 51, no. 1-3, 31 August 1998 (1998-08-31), pages 121-130. XP004153998 ISSN: 0925-4005
 - D2: GIBSON C A ET AL: 'Kinetic factors in the response of piezo-optical chemical monitoring devices' SENSORS AND ACTUATORS B, ELSEVIER SEQUOIA S.A., LAUSANNE, CH, vol. 51, no. 1-3, 31 August 1998 (1998-08-31), pages 238-243, XP004154016 ISSN: 0925-4005
 - D3: FR-A-2 715 226 (UNIV REIMS CHAMPAGNE ARDENNE)
 - D4: WO 90/13017 A (HEALTH LAB SERVICE BOARD) cited in the application

2. Novelty (Art. 33(2) PCT) and Inventive Step (Art. 33(3) PCT):

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 1-5**, **8-13 and 16** is not new in the sense of Article 33(2) PCT, and because the subject-matter of **claims 1-25** does not involve an inventive step in the sense of Article 33(3) PCT.

2.1 <u>Independent apparatus claim 1</u>:

- 2.1a D1 and D2 disclose (the references in parentheses applying to these documents):
 - -- A device for detecting energy (heat) generated by non-radiative decay in an analyte (e.g. ammonia) on irradiation with electromagnetic radiation (**D1**: title; abstract; fig. 2)(**D2**: title, abstract; fig. 1);
 - -- a radiation source (LED) adapted to generate a series of pulses of electromagnetic radiation (**D1**: fig. 2; page 121, right column, lines 16-17, "chopped light"; page 124, left column, lines 1-3)(**D2**: fig. 1; page 238, left column, lines 20-21, "chopped light");

- -- a transducer having a pyroelectric *or* piezoelectric element and electrodes *which is capable of* transducing the energy (heat) generated by the substance into an electrical signal (**D1**: fig. 2, "PVDF film"; abstract; page 121, right column, lines 1-7)(**D2**: fig. 1, "PVDF film"; abstract; page 238, left column, line 18, right column, lines 1-3);
- -- at least one reagent proximal to the transducer, the reagent having a binding site which is *capable of* binding the analyte (**D1**: page 121, right column, line 5)(**D2**: fig. 1; p. 238, left column, lines 17-18: reagent spots; p. 238, right column, lines 10-11; p. 243, right col. I. 5-8);
- -- a detector which is capable of detecting the electric signal generated by the transducer (**D1**: implicitly disclosed on page 121, right column, lines 7-10)(**D2**: implicitly disclosed on page 238, right column, lines 3-5);
- -- the detector is *adapted to*** determine the time delay between each pulse of electromagnetic radiation from the radiation source and the generation of the electric signal (**D1**: page 122, left column, lines 14-16; page 124, left column, lines 1-9, "variable phase lag")(**D2**: title, "kinetic factors"; fig. 3 shows detected signals as the distance of the heat source from the transducer is varied; fig. 4 shows the "phase lags").

It should be noted that D2 is directly referred to in D1 (see page 124, left column, par. 5, "Phase lag... Details of this behaviour are given elsewhere [4]". For the discussion on patentability, both documents can therefore also be seen as one document, whereby the information disclosed in D2 is implicitly disclosed in D1.

- ** The expression "adapted to" has to interpreted as meaning "suitable for" (see the PCT/GL/ISPE/1, 5.23). The detector disclosed in D1 and D2 is used for introducing phase-lags and for setting time windows for measurement, hence said detector comprises all technical means which render said detector "adapted to" determine various phase delays.
- 2.1b It should be noted, that **D4**, cited in the application, also discloses (the references in parentheses applying to this document):
 - -- A device for detecting energy generated by non-radiative decay in an analyte on irradiation with electromagnetic radiation (fig. 1);

- -- a radiation source 24 *adapted to* generate a series of pulses of electromagnetic radiation (page 5, lines 22-27);
- -- a transducer 10 having a pyroelectric *or* piezoelectric element and electrodes 12, 14 *which is capable of* transducing the energy generated by the substance into an electrical signal (page 5, lines 10-11, 32-37);
- -- at least one reagent 16 (reagent dots) proximal to the transducer 10, the reagent 16 having a binding site which is *capable of* binding the analyte (abstract; page 6, l. 8-17);
- -- a detector which is capable of detecting the electric signal generated by the transducer (implicitly disclosed in page 5, line 36 page 6, line 5, "microcomputer");
- -- the detector is *adapted to* (see the comment ** for **D1/D2** above) determine the time delay between each pulse of electromagnetic radiation from the radiation source and the generation of the electric signal (implicitly disclosed in page 4, lines 17-19: "the depth... that is probed"; page 5, lines 25-28; page 6, lines 1-3, "reference signal" of light modulation via "line 28" to "phase-locked" detector).
- 2.1c Hence, claim 1 is not new (Art. 33(2) PCT) with respect to D1, D2 and/or D4.
- 2.1d **D3** discloses (the references in parentheses applying to this document):
 - -- A device *for* detecting energy generated by non-radiative decay in a *substance* on irradiation with electromagnetic radiation (fig. 1, 2; page 4, lines 5-34; page 5, line 23 page 6, line 16);
 - -- a radiation source 1 *adapted to* generate a series of pulses 3 of electromagnetic radiation F (page 5, lines 24-31; page 4, lines 10-16);
 - -- a transducer 4 having a pyroelectric *or* piezoelectric element and electrodes *which is capable of* transducing the energy generated by the substance into an electrical signal (page 6, lines 3-7; page 4, lines 17-19);
 - -- a detector 5, 6, 7 which is capable of detecting the electric signal generated by the transducer (page 6, lines 7-13; page 4, lines 20-22);
 - -- the detector 7 is *adapted to* (see the comment ** for **D1/D2** above) determine the time delay between each pulse of electromagnetic radiation from the radiation source and the generation of the electric signal (page 6, lines 13-14; page 4, lines 23-27; page 8, lines 11-14, 24-25; fig. 7).

Claim 1 differs from D3 in that a reagent having a binding site capable of binding an analyte is provided proximal the transducer is additionally defined.

Although a <u>preferred embodiment</u> of D3 concentrates on measuring the change in the physical properties of a layer built up in proximity to the pyroelectric film (p. 13, l. 22-25), D3 is well-suited for measuring or analysing the properties of <u>any</u> solid, liquid or gaseous material which can be generally characterized in layers (p. 1, l. 1-10). <u>The skilled person is not restricted to this or a particular application</u>. The apparatus of D3 can, for example, also be used for various other applications such as detecting bacteria or <u>movement of cells</u> (p. 14, l. 17-22) proximal the transducer.

The **objective technical problem** of the invention can therefore be seen as to find (even more) applications for the apparatus known from D3.

The **solution** or <u>particular application</u> (monitoring a solid/liquid material, i.e. a binding layer proximal to a transducer and a solution comprising an analyte contacting the reagent layer, which can be generally characterized in layers) proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT), since it is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

2.2 <u>Independent method claim 17</u>:

What has been said above with reference to apparatus claim 1 and with respect to **D1-D4** concerns method claim 17 mutatis mutandis.

It should be noted that it is explicitly mentioned in D2 (see for example p. 243, lines 1-10) that "as the number of layers (or distance) increases, the phase lag increases because the heat is generated further from the PVDF interface". In other words, as the distance between the transducer of D1/D2 and the location of the heat generating source (i.e. analyte or bound complex of the analyte) increases, the time lag also increases.

Therefore, it would be obvious for the skilled person to <u>apply this information</u> and to use the detector of D1/D2 (which is adapted to detect time delays, see ** above) for detecting time delays and for **correlating** said time delays "to the position of the

analyte at any of one or more positions at different distances from the surface of the transducer", in particular with respect to the time delay measurements for multilayer characterisation proposed in D3.

Hence, claim 17 does not involve an inventive step (Art. 33(3) PCT).

- 2.4 Dependent claims 2-16 and 18-25 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see documents D1-D4 and the corresponding passages cited in the search report:
 - Claim 2, 18: reagent is antibody (D4: page 6, line 15)(obvious with respect to D2, fig. 1; page 243, right column, lines 5-8);
 - Claims 3, 4, 5, 12: no clearly claimed apparatus features; the substance/analyte does not form part of the claimed device;
 - Claims 6, 7, 15: reagent is a first nucleic acid; the reagent contains avidin or derivatives thereof (obvious with respect to D2, fig. 1, page 243, right column, lines 5-8; and D4: page 6, lines 8-17);
 - Claims 8, 9: time delay is at least 5 ms; no greater than 500 ms (D2: fig. 4);
 - Claim 10: light (D1: page 121, right column, line 17)(D2: page 238, left column, line 21)(D3: page 5, line 25)(D4: page 5, lines 22-23);
 - Claims 11: reagent is adsorbed on to the transducer (D1: page 121, right column, line 5)(D2: fig. 1; page 243, right column, lines 5-8)(D4: fig. 1, reagent 16);
 - Claim 13: well for holding the liquid in contact in contact with the transducer (D1: page 122, right column, lines 21-23: pores)(D3: fig. 5);
 - Claim 14: chamber for storing additional reagents (non-inventive design option);
 - Claims: 16, 25: pulses at least 2 Hz (see for example D4, page 5, lines 25-27);
 - Claims 19-23: complex with labelled antibody, antigen, ... (obvious with respect to D2, fig. 1, page 243, right column, lines 5-8; and D4: page 6, lines 8-17);
 - Claim 24: see D1-D4.
- 3. Industrial applicability (Article 33(4) PCT):

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

International application No.

PCT/GB2004/001551

The requirement of Art. 33(4) PCT as to industrial applicability is fulfilled for all claims.

Re Item VII

Certain defects in the international application (form or content)

- 4.1 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1, D2 and D3 is not mentioned in the description, nor are these documents identified therein.
- 4.2 The features of the claims are not provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).
- 4.3 According to the requirements of Rule 11.13(I) reference signs not appearing in the description shall not appear in the drawings, and vice versa. This requirement is not met in view of the **reference sign "13"**, page 7, third paragraph (not in fig. 2).

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Claims

- 1. A device for detecting energy generated by non-radiative decay in an analyte or a complex or derivative of the analyte on irradiation with electromagnetic radiation comprising
- a radiation source adapted to generate a series of pulses of electromagnetic radiation, a transducer having a pyroelectric or piezoelectric element and electrodes which is capable of transducing the energy generated by the substance into an electrical signal, at least one reagent proximal to the transducer, the reagent having a binding site which is capable of binding the analyte or the complex or derivative of the analyte, and
- a detector which is capable of detecting the electrical signal generated by the transducer,
- wherein the detector is adapted to determine the time delay between each pulse of electromagnetic radiation from the radiation source and the generation of the electric signal.
 - 2. A device as claimed in claim 1, wherein the reagent is an antibody and the analyte is an antigen.
 - 3. A device as claimed in claim 2, wherein the complex or derivative of the analyte is a complex with a labelled antibody.
- 4. A device as claimed in claim 2, wherein the analyte is a labelled antigen and the electrical signal detected by the detector is inversely proportional to the presence of an unlabelled antigen in the sample.
 - 5. A device as claimed in claim 3 or 4, wherein the labelled antibody or antigen is labelled with a label selected from a dye molecule, a gold particle, a coloured-polymer particle, a fluorescent molecule, an enzyme, a red blood cell, a haemoglobin molecule, a magnetic particle and a carbon particle.

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- 6. A device as claimed in claim 1, wherein the reagent is a first nucleic acid and the analyte is a second nucleic acid and the first and second nucleic acids are complementary.
- 7. A device as claimed in claim 1, wherein the reagent contains avidin or derivatives thereof and the analyte contains biotin or derivatives thereof, or vice versa.
 - 8. A device as claimed in any preceding claim, wherein the time delay is at least 5 milliseconds, preferably at least 10 milliseconds.
 - 9. A device as claimed in any preceding claim, wherein the time delay is no greater than 500 milliseconds, preferably no greater than 250 milliseconds, more preferably no greater than 150 milliseconds.
- 15 10. A device as claimed in any preceding claim, wherein the electromagnetic radiation is light, preferably visible light.
 - 11. A device as claimed in any preceding claim, wherein the reagent is adsorbed on to the transducer.
 - 12. A device as claimed in any preceding claim, wherein the analyte is dissolved or suspended in a liquid.
- 13. A device as claimed in claim 12, further comprising a well for holding the25 liquid in contact with the transducer.
 - 14. A device as claimed in any preceding claim, further comprising a chamber for storing one or more additional reagents.
- 30 15. A device as claimed in claim 14, wherein the additional reagent is a labelled antibody for producing the subsequently formed complex or derivative of the analyte.

- 16. A device as claimed in any preceding claim, wherein the frequency of the pulses of electromagnetic radiation is at least 2 Hz.
- 5 17. A method for detecting an analyte in a sample, comprising the steps of exposing the sample to a transducer having a pyroelectric or piezoelectric element and electrodes which is capable of transducing a change in energy to an electrical signal, the transducer having at least one reagent proximal thereto, the reagent having a binding site which is capable of binding the analyte or a complex or derivative of the analyte, the analyte or the complex or derivative of the analyte being capable of absorbing the electromagnetic radiation generated by the radiation source to generate energy by non-radiative decay;

irradiating the reagent with a series of pulses of electromagnetic radiation, transducing the energy generated into an electrical signal;

detecting the electrical signal and the time delay between each pulse of electromagnetic radiation from the radiation source and the generation of the electric signal, wherein the time delay between each of the pulses of electromagnetic radiation and the generation of the electric signal corresponds to the position of the analyte at any of one or more positions at different distances from the surface of the transducer.

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- 18. A method as claimed in claim 17, wherein the reagent is an antibody and the analyte is an antigen.
- 19. A method as claimed in claim 18, wherein the complex or derivative of the analyte is a complex with a labelled antibody.
 - 20. A method as claimed in claim 18, wherein the analyte is a labelled antigen and the electrical signal detected by the detector is inversely proportional to the presence of an unlabelled antigen in the sample.

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21. A method as claimed in claim 19 or 20, wherein the labelled antibody or antigen is labelled with a label selected from a dye molecule, a gold particle, a

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coloured-polymer particle, a fluorescent molecule, an enzyme, a red blood cell, a haemoglobin molecule, a magnetic particle and a carbon particle.

- 22. A method as claimed in claim 17, wherein the reagent is a first nucleic acid and the analyte is a second nucleic acid and the first and second nucleic acids are complementary.
 - 23. A method as claimed in claim 17, wherein the reagent contains avidin or derivatives thereof and the analyte contains biotin or derivatives thereof, or vice versa.
 - 24. A method as claimed in any of claims 17 to 23, wherein the method is carried out without removing the sample from the transducer between the steps of exposing the sample to the transducer and irradiating the reagent.
- 15 25. A method as claimed in any of claims 17 to 24, wherein the frequency of the pulses of electromagnetic radiation is at least 2 Hz.

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER IPC 7 G01N21/17 G01N G01N25/48 G01N33/487 G01N33/53 According to International Patent Classification (IPC) or to both national classification and IPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) IPC 7 G01N Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the International search (name of data base and, where practical, search terms used) EPO-Internal, PAJ, WPI Data, BIOSIS, INSPEC C. DOCUMENTS CONSIDERED TO BE RELEVANT Category of Citation of document, with indication, where appropriate, of the relevant passages Relevant to dalm No. X WO 90/13017 A (HEALTH LAB SERVICE BOARD) 1-10, 1 November 1990 (1990-11-01) 13-15. cited in the application 18-29 page 4, line 17 - line 19 page 5, line 10 -page 6, line 24; figure 1 X GIBSON C A ET AL: "Kinetic factors in the 1,2,9, response of piezo-optical chemical 11-16, monitoring devices" 19,20, SENSORS AND ACTUATORS B, ELSEVIER SEQUOIA 27,28 S.A., LAUSANNE, CH. vol. 51, no. 1-3. 31 August 1998 (1998-08-31), pages 238-243, XP004154016 ISSN: 0925-4005 the whole document Further documents are listed in the continuation of box C. Patent family members are listed in annex. Special categories of cited documents: *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the 'A' document defining the general state of the art which is not considered to be of particular relevance invention *E* earlier document but published on or after the international "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone filing date "L" document which may throw doubts on priority claim(s) or which is clied to establish the publication date of another cliation or other special reason (as specified) "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "O" document referring to an oral disclosure, use, exhibition or *P* document published prior to the international filing date but later than the priority date claimed In the art. "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 15 July 2004 26/07/2004 Name and mailing address of the ISA Authorized officer European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016 Duijs, E

INTERNATIONAL SEARCH REPORT

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| C.(Continu | ation) DOCUMENTS CONSIDERED TO BE RELEVANT | PC1/GB2004/001551 |
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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